

REMARKS

This amendment is responsive to the Office Action mailed August 2, 2006 in connection with the above-identified patent application. Claims 1, 3-24, and 26-65 are pending in this application. Claims 12-23 and 29-40 have been withdrawn from consideration.

In the Office Action, all pending claims were rejected. Claims 47 and 48 were objected to because of an informality identified by the Examiner in the Action. Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 3, 6-11, 24, 26-28, 41-43, 46-53, and 56-65 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,951,539 to Nita, et al (hereinafter "Nita"). Lastly in the Action, claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of U.S. Patent No. 5,728,065 to Follmer, et al. (hereinafter "Follmer").

THE NON-ART REJECTIONS

As noted above, claims 47 and 48 were objected to because of an informality. More particularly, claims 47 and 48 recite the limitation of a "continuous coil reinforcement member" in line 2 and, according to the Examiner, there is insufficient antecedent basis for this limitation in the claims.

In addition to the above, claims 4, 5, 44, 45, 54, and 55 were rejected under 35 U.S.C. § 112, second paragraph. According to the Examiner, those claims are indefinite and fail to particularly point and distinctly claim the subject matter which applicant regards as the invention. With regard to claims 4, 44, and 54, it was unclear to the Examiner on which outer coating, i.e. the first or second outer coating, the marker band is disposed.

Claims 47 and 48 are in Proper Form:

Applicant has tendered an amendment to dependent claims 47 and 48 above wherein the expression "the continuous coil reinforcement member" has been

changed to "the coil reinforcement member" because there is clear and unambiguous antecedent basis in independent claim 1 for the "coil reinforcement member" limitation.

For at least the above reason, it is respectfully submitted that claims 47 and 48 are in proper form.

Claims 4, 5, 44, 45, 54, and 55 are in Condition for Allowance Under 35 U.S.C. § 112:

As noted above, claims 4, 5, 44, 45, 54, and 55 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. According to the Examiner, it was unclear on which outer coating the marker bag is disposed.

Applicant has amended each of claims 4, 44, and 14 to include the clarification that the marker band is disposed on the first flexible outer coating rather than on the second flexible outer coating covering a first portion of the first outer coating. This is shown in at least Figure 4d of the drawings and described in the specification of the instant application. Claims 5, 45, and 55 depend respectively from claims 4, 44, and 54.

According to the above, therefore, it is respectfully submitted that claims 4, 5, 44, 45, 54, and 55 are now in condition for allowance under 35 U.S.C. § 112.

THE ART REJECTIONS

With reference yet once again to the Office Action, all pending claims stand rejected. Claims 47 and 48 were objected to because of an informality identified by the Examiner in the Action. Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 3, 6-11, 24, 26-28, 41-43, 46-53, and 56-65 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,951,539 to Nita, et al (hereinafter "Nita"). Lastly in the Action, claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of U.S. Patent No. 5,728,065 to Follmer, et al. (hereinafter "Follmer").

The Present Application:

A first embodiment of the invention is directed to a reinforced catheter apparatus (claims 1, 3-11, and 41-51) and a second embodiment of the invention is directed to a reinforced catheter stock for manufacturing reinforced catheters (claims 24 and 26-28). The first and second embodiments of the invention forms the instant application are the subject of this prosecution and of the instant amendment. A third embodiment of the invention is directed to a method of manufacturing multiple reinforced catheters (claims 12-23), and a method of manufacturing a reinforced catheter stock (claims 29-33), and a fourth embodiment is directed to an apparatus for manufacturing the reinforced catheter stock (claims 34-40). The third and fourth embodiments of the invention in the instant application are not the subject of this prosecution or amendment and have been previously withdrawn.

As noted above, a first embodiment of the invention is directed to a reinforced catheter apparatus. Essentially, the apparatus includes an elongate tubular member carrying a continuous coil reinforcement member thereon from end to end. First and second layers of outer coatings are disposed onto the tubular member and coil reinforcement in turn so that the first material forms a first layer thereon and the second material forms a second layer on the first material. The inner first material is softer than the outer second material. A portion of the second outer coating is ground away to form a flexible distal tip portion of the catheter. The coil reinforcement member is present in the distal tip portion of the catheter between the tubular member and the inner first material.

The reinforced catheter apparatus 68 is shown in Figure 4b as amended and is described in the specification, particularly at page 14. The reinforced catheter 68 comprises an elongate flexible tubular member 51 defining a lumen of the catheter, a continuous coil reinforcement member 54 (Fig. 2c) carried on the elongate flexible tubular member 51, a first flexible outer coating 58 covering the coil reinforcement member 54, and a second flexible outer coating 62 covering a first portion 74 of the first outer coating 58. The elongate flexible tubular member 51 defining the lumen of the catheter has a first end defining a proximal end 69 of the catheter, and a second end

defining a distal end 67 of the catheter. The continuous coil reinforcement member 54 (Fig. 2c) carried on the elongate flexible tubular member 51 extends from the proximal end 69 of the catheter to the distal end 67 of the catheter and to the second end of the tubular member. The first outer coating 58 covers the coil reinforcement member 54 and the tubular member 51 substantially entirely between the proximal end 69 of the catheter and the distal end 67 of the catheter. The second flexible outer coating 62 covers a first portion 74 of the first outer coating 58 between a first transition area 73 of the catheter and the proximal end 69 of the catheter. A second portion 72 of the first outer coating 58 is uncovered by the second outer coating 62 and defines a flexible tip 72 of the catheter. Lastly, in the first preferred embodiment, the first outer coating 58 is softer than the second outer coating 62.

In another form, a reinforced catheter 68 is provided comprising an elongate flexible tubular member 51 defining a lumen of the catheter, the tubular member 51 having a first end defining a proximal end 69 of the catheter and a second end defining a distal end 67 of the catheter. A first flexible outer coating 58 covers the tubular member 51 fully between the proximal end 69 of the catheter to the distal end 67 of the catheter. A second flexible outer coating 62 covers a first portion 74 of the first outer coating 58 with a second portion 72 of the first outer coating 58 being uncovered by the second outer coating 62 and defining a flexible distal tip 67 of the catheter. The first coating 58 is softer than the second coating 62. A coil reinforcement member 54 (Fig. 2c) is carried on the elongate flexible tubular member 51 and is disposed at the distal tip 67 of the catheter and extends to and terminates at the second end of the tubular member.

In accordance with a second embodiment of the application, a reinforced catheter stock is provided for forming multiple catheters therefrom. The catheter stock includes a tubular member carrying a continuous coil reinforcement member thereon. First and second buildups of first and second material layers are disposed thereon wherein the first inner layer is softer than the second outer layer. The catheter stock may be cut into pieces to provide catheters having selected lengths as desired.

In the second embodiment of the application, the reinforced catheter stock 64 is provided for manufacturing reinforced catheters. The catheter stock 64 is constructed in accordance with a method as set out in the specification and shown in flow chart form in Fig. 1. It is to be appreciated that selected method steps from Fig. 1 are illustrated in various drawing figures including Figs. 2a-2f. The end product resultant from the method shown in Fig. 1 is a reinforced catheter stock construction 64 as shown in Fig. 2f. More particularly, the reinforced catheter stock 64 (Fig. 2f) comprises a selected length of an elongate flexible tubular member 51 (Fig. 2a) defining a lumen of the catheter stock. The tubular member has a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock. A continuous coil reinforcement member 54 (Figs. 2b-2f) is carried on the elongate flexible tubular member 51 (Figs. 2b-2f) and extends from the lead end of the catheter stock to the trailing end of the catheter stock. A continuous outer coating of a first material 58 (Fig. 2e) covers the coil reinforcement member 54 and the tubular member substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock. Further, a continuous outer coating of a second material 62 (Fig. 2f) covers the continuous outer coating of the first material 58 substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock. In the second embodiment of the invention, the first material 58 is softer than the second material 62.

U.S. Patent No. 5,951,539 to Nita, et al.:

U.S. Patent No. 5,951,539 to Nita, et al. teaches a surgical device, namely a catheter, suitable for accessing a tissue target within a human body, typically a target which is accessible through the vascular system. Central to the invention taught in Nita is the use of at least a pair of wound or counter wound reinforcing members situated within the wall of the catheter body.

As stated in the Nita patent at column 7, lines 41-46, the invention is a catheter having two or more spirally wound reinforcement ribbons or wires, preferably

stainless steel, typically placed between an outer polymeric covering and an inner lubricious polymeric liner, sometimes interspersed with other filler layers or sections.

Essentially, in the Nita patent, as set out at column 8, lines 60 and 61, the design includes at least a pair of helically wound stiffener members coaxial with both the polymeric outer and the inner lubricious layer. The stiffness members extend toward but not completely to the tip/end of the catheter body.

In one embodiment shown in Figure 4, the catheter is formed of numerous sections of increasing stiffness proximally wherein section 304 is more stiff than section 302, section 306 is more stiff than section 304, and, lastly, section 308 is more stiff than section 306. Figure 9 of the Nita patent shows well the distal tip portion 520 of the catheter in which helically wound coils 522, 524 extend distally to the tip or toward a bumper portion 526. As described at the bottom of column 15 of the Nita patent, the distal tip or bumper portion 526 is relatively short, typically having a length of no more than about 10-15 times the diameter of the device. Most significantly, however, is that the Nita patent notes at column 15, lines 65-67 that the expression that "a coil extends to the distal end of the catheter" is intended to mean in effect that the coil extends toward the distal end of the catheter but that the catheter necessarily includes the presence of a bumper tip 526 as shown in Figure 9 which, as noted above, carries no coil reinforcement members therein.

U.S. Patent No. 5,728,065 to Follmer, et al.:

U.S. Patent No. 5,728,065 to Follmer, et al. teaches a balloon catheter comprising a catheter body having an elastomeric balloon at its distal end. Figure 2 in the Follmer patent shows a radiopaque marker ring which is embedded within a soft tip 122 of the balloon catheter 100 shown there.

Claims 1 and 3-11 are in Condition for Allowance:

Claims 1, 3, and 6-11 were rejected as being anticipated by Nita and claims 4 and 5 were rejected as being unpatentable over Nita in view of Follmer.

Applicant has amended independent claim 1 to recite a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the catheter, a first flexible outer coating covering the coil reinforcement member, and a second flexible outer coating covering a first portion of the first outer coating. Also, the claim includes the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to the Nita patent at column 6, lines 11-15 which suggest that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to the Nita patent at column 14, lines 36-57 which describe an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 1, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Follmer patent does not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, it is respectfully submitted that independent claim 1 and claims 3-11 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 24 and 26-28 are in Condition for Allowance:

Independent claim 24 has been amended to clarify the claim in that the continuous coil reinforcement member element of the claimed reinforcement catheter stock is carried on the elongate flexible tubular member and extends from the lead end of the catheter stock to the trailing end of the catheter stock entirely. Applicants intend for this language to include the limitation that the continuous coil reinforcement member extends up to and terminates at the trailing end of the catheter stock as well as up to and at the lead end of the catheter stock. Simply, the continuous coil reinforcement member extends from end to end of the catheter stock.

As stated in the Nita patent at column 7, lines 41-46, the invention is a catheter having two or more spirally wound reinforcement ribbons or wires, preferably

stainless steel, typically placed between an outer polymeric covering and an inner lubricious polymeric liner, sometimes interspersed with other filler layers or sections.

Essentially, in the Nita patent, as set out at column 8, lines 60 and 61, the design includes at least a pair of helically wound stiffener members coaxial with both the polymeric outer and the inner lubricious layer.

In one embodiment shown in Figure 4, the catheter is formed of numerous sections of increasing stiffness proximally wherein section 304 is more stiff than section 302, section 306 is more stiff than section 304, and, lastly, section 308 is more stiff than section 306. Figure 9 of the Nita patent shows well the distal tip portion 520 of the catheter in which helically wound coils 522, 524 extend distally to the tip or toward a bumper portion 526. As described at the bottom of column 15 of the Nita patent, the distal tip or bumper portion 526 is relatively short, typically having a length of no more than about 10-15 times the diameter of the device. Most significantly, however, is that the Nita patent notes at column 15, lines 65-67 that the expression that "a coil extends to the distal end of the catheter" is intended to mean in effect that the coil extends toward the distal end of the catheter but that the catheter necessarily includes the presence of a bumper tip 526 as shown in Figure 9 which, as noted above, carries no coil reinforcement members therein.

For at least the above reasons, it is respectfully submitted that independent claim 24 and claims 26-28 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 41-51 are in Condition for Allowance:

Applicant has amended independent claim 41 to include the limitations of claim 42 wherein the coil reinforcement member element of the recited reinforced catheter is carried on the elongate flexible tubular member and extends from said first end of the tubular member and terminates at said second end of the tubular member.

As stated in the Nita patent at column 7, lines 41-46, the invention is a catheter having two or more spirally wound reinforcement ribbons or wires, preferably

stainless steel, typically placed between an outer polymeric covering and an inner lubricious polymeric liner, sometimes interspersed with other filler layers or sections.

Essentially, in the Nita patent, as set out at column 8, lines 60 and 61, the design includes at least a pair of helically wound stiffener members coaxial with both the polymeric outer and the inner lubricious layer.

In one embodiment shown in Figure 4, the catheter is formed of numerous sections of increasing stiffness proximally wherein section 304 is more stiff than section 302, section 306 is more stiff than section 304, and, lastly, section 308 is more stiff than section 306. Figure 9 of the Nita patent shows well the distal tip portion 520 of the catheter in which helically wound coils 522, 524 extend distally to the tip or toward a bumper portion 526. As described at the bottom of column 15 of the Nita patent, the distal tip or bumper portion 526 is relatively short, typically having a length of no more than about 10-15 times the diameter of the device. Most significantly, however, is that the Nita patent notes at column 15, lines 65-67 that the expression that "a coil extends to the distal end of the catheter" is intended to mean in effect that the coil extends toward the distal end of the catheter but that the catheter necessarily includes the presence of a bumper tip 526 as shown in Figure 9 which, as noted above, carries no coil reinforcement members therein.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to the Nita patent at column 6, lines 11-15 which suggest that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first

coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to the Nita patent at column 14, lines 36-57 which describe an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 41, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 41 of the present application.

In addition to the above, the Follmer patent does not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, independent claim 41 and claims 42-52 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 52-60 are in Condition for Allowance:

Independent claim 52 recites a reinforced catheter comprising an elongate flexible tubular member having first and second ends and defining a lumen of the catheter, a continuous coil reinforcement member on the elongate flexible tubular

member and terminating at said first and second ends of the tubular member, and first and second flexible outer coatings, the second flexible outer coating covering a first portion of the first flexible outer coating and the first flexible outer coating being softer than said second coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to the Nita patent at column 6, lines 11-15 which suggest that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to the Nita patent at column 14, lines 36-57 which describe an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 52, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure

As to the first point above, the Examiner cites to the Nita patent at column 6, lines 11-15 which suggest that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to the Nita patent at column 14, lines 36-57 which describe an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 61, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 61 of the present application.

In addition to the above, the Follmer patent does not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Follmer patent does not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, applicant respectfully submits that independent claim 52 and claims 53-60 dependent therefrom are patentably distinct and unobvious over the references of record.

Claims 61-64 are in Condition for Allowance:

Independent claim 61 has been amended to clarify the extent to which the coil reinforcement member extends on the elongate flexible tubular member comprising the reinforced catheter of the claim. More particularly, the coil reinforcement member element of the recited reinforced catheter includes the limitation of the reinforcement member being carried on the elongate flexible tubular member and extending in said distal tip of the catheter completely to said second end of the elongate flexible tubular member. In addition, the reinforced catheter claimed includes first and second outer coatings, the second outer coating covering a first portion of the first outer coating and the first coating being softer than the second coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

For at least the above reasons, it is respectfully submitted that independent claim 61 and claims 62-64 dependent therefrom are patentably distinct and unobvious over the references of record.

Claim 65 is in Condition for Allowance:

Applicant has tendered an amendment to independent claim 65 to recite a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member on the elongate flexible tubular member and extending completely to and terminating at said second end of the tubular member, and first and second outer coatings, the second outer coating covering a first portion of the first outer coating and the first outer coating being softer than the second outer coating.

Claims 1, 3, and 6-11 were rejected as being anticipated by Nita and claims 4 and 5 were rejected as being unpatentable over Nita in view of Follmer.

Applicant has amended independent claim 1 to recite a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the catheter, a first flexible outer coating covering the coil reinforcement member, and a second flexible outer coating covering a first portion of the first outer coating. Also, the claim includes the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to the Nita patent at column 6, lines 11-15 which suggest that an outer layer may have a wide variety of material

chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to the Nita patent at column 14, lines 36-57 which describe an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 65, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Follmer patent does not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, applicant respectfully submits that independent claim 65 is patentably distinct and unobvious over the references of record.

CONCLUSION

In view of the above amendments, comments, and arguments presented, it is respectfully submitted that all pending claims are patentably distinct and unobvious over the references of record.

Allowance of all pending claims and early notice to that effect is respectfully requested.

Respectfully submitted,

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02/01/06
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CERTIFICATE OF MAILING OR TRANSMISSION

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